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In the Supreme Court of the United States

OCTOBER TERM, 1966

No. 39

ABBOTT LABORATORIES, ET AL., PETITIONERS

v.

JOHN W. GARDNER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND JAMES L. GODDARD, COMMISSIONER OF FOOD AND DRUGS

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE RESPONDENTS

OPINIONS BELOW

The opinion of the court of appeals (R. 66–74) is reported at 352 F. 2d 286. The opinion of the district court (R. 41–55) is reported at 228 F. Supp. 855.

JURISDICTION

The judgments of the court of appeals were entered on November 1, 1965 (R. 65, 74–75). The petition for a writ of certiorari was filed on December 15, 1965, and was granted on February 28, 1966 (R. 75; 383 U.S. 924). The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether interpretive regulations issued by respondents with respect to the provisions of the 1962 Drug Amendments to the Federal Food, Drug and Cosmetic Act may be challenged by petitioners, prior to enforcement, in an action seeking declaratory and injunctive relief.

2. Whether the regulations properly construe the provisions of the 1962 amendments.

3. Whether corporations doing business in a State but not incorporated therein may bring a civil suit in that State against federal officers under 28 U.S.C. 1391(e)(4).

STATUTES AND REGULATION INVOLVED

The relevant statutes and regulation appear in the Appendix, *infra*, pp. 67–74.

STATEMENT

Section 502(e)(1)(B) of the Federal Food, Drug and Cosmetic Act, enacted as part of the Drug Amendments of 1962, 76 Stat. 780, 790, requires "the established name" of any prescription drug to be "printed prominently" on any label and on any labeling in which any proprietary name of the drug appears "in type at least half as large as that used thereon for any proprietary name or designation for such drug" (p. 68, *infra*). Since there are drugs with one established name but different trade names—*e.g.*, "meprobamate" (sold under that name as well as under the proprietary names "Miltown" and "Equanil")—Congress adopted the above provision and Section 502(n)

(1)[1] to bring to the attention of prescribing physicians the established as well as the proprietary name under which a drug is promoted and thereby to encourage physicians to prescribe the least expensive drug to their patients.[2]

On February 14, 1963, the Commissioner of Food and Drugs, invoking his authority to promulgate regulations for the "efficient enforcement" of the Act (Section 701(a), 21 U.S.C. 371(a), p. 69, *infra*) and exercising his discretion to invite public participation in their formulation (see Section 4 of the Administrative Procedure Act, as recodified, 5 U.S.C. 553), announced proposed regulations. These regulations provided that the established or generic name of a prescription drug accompany each appearance of any trade name on labels, labeling and advertising. 28 Fed. Reg. 1448. The Pharmaceutical Manufacturers Association ("PMA") and several of its member firms submitted written comments, challenging the proposed interpretation as contrary to the statutory purpose. No requests for exemption on the basis of a showing of impracticability were made (Section 502(e)(1)

[1] Section 502(n)(1) requires "the established name" to appear in all advertisements and descriptive matter issued with respect to the drug and for it "to be printed prominently and in type at least half as large as that used for any trade or brand name thereof" (p. 69, *infra*).

[2] The evidence before Congress showed that drugs purchased under their established names cost one-third or one-half less than the same drug sold under the proprietary names. See 108 Cong. Rec. 17367–17368, 17381–17383. See also the views of Senators Kefauver, Dodd, Carroll, Hart, and Long. S. Rept. No. 1744, Part I, 87th Cong., 2d Sess., pp. 33–36, 38–39, 46–51.

(B)). The regulations were adopted in final form on June 20, 1963, 28 Fed. Reg. 6375.

In September 1963, PMA and 37 of its members (R. 4–7), instituted suit in the United States District Court for the District of Delaware under the Declaratory Judgments and Administrative Procedure Acts (pp. 67–68, *infra*), seeking a declaration that the "every time" interpretation embodied in the regulations (21 C.F.R. 1.104(g)(1); 21 C.F.R. 1.105(b)(1); pp. 73–74, *infra*) constituted an unwarranted expansion of statutory authority and requesting an injunction against enforcement of the regulations (R. 4–18). The plaintiffs alleged, *inter alia,* that the "every time" requirement would adversely affect the readability of their promotional material and that compliance with the regulations would make a substantial proportion of their promotional material unusable and require major revision at substantial expense (R. 14–16). Respondents moved to dismiss on the ground, *inter alia,* that the complaint failed to allege an "actual controversy" cognizable under the Declaratory Judgments Act (R. 18–21).

On cross-motions for summary judgment (R. 18–21, 22–23), the district court ruled that venue was improper for 26 of the corporate plaintiffs which were not incorporated in Delaware (R. 43–46), but otherwise granted the relief sought by petitioners (R. 62–63). The court found that the existence of the regulations posed a threat of imminent harm to petitioners and were "ripe" for judicial review (R. 48–50). Holding on the merits that the "every time" requirement was inconsistent with the statutory command

(R. 51–55), the court declared the regulations invalid and enjoined respondents from enforcing them by any administrative action or civil or criminal proceeding (R. 62–63).

The court of appeals affirmed as to the venue ruling (352 F. 2d 524), but otherwise reversed the judgment of the district court. Without reaching the question of the validity of the regulations, the court of appeals held that judicial review was unavailable at this juncture because: (1) it found in the statutory scheme a Congressional intent to preclude judicial review of the type of regulations here involved "prior to the enforcement stage" (R. 70)[1] and (2) because the fact that there was "[n]o specific case * * * presented, no immediate prosecution threatened" (R. 72) meant that there was no "'actual case or controversy' required for justiciability" under the Declaratory Judgments and Administrative Procedure Acts (R. 73–74).

SUMMARY OF ARGUMENT

I

A. The judicial review provisions of the Food, Drug and Cosmetic Act of 1938 expressly authorize pre-enforcement review only with respect to certain enumerated kinds of regulations. The specified regulations are "legislative" in character—*i.e.*, they constitute an exercise by the Food and Drug Adminis-

[1] An "enforcement" proceeding (by way of injunction, seizure or criminal prosecution) may be instituted by the Attorney General on a charge of misbranding. Particularized review may also arise through review of administrative orders relating to new drug clearance (Section 505, 21 U.S.C. 355) and antibiotic certification (Section 507, 21 U.S.C. 357).

tration of a delegated power to fill in the details of a statutory provision. Review of "interpretive" regulations—*i.e.*, those which announce the agency's understanding of a statutory rule—are not explicitly made reviewable, and we submit that an examination of the legislative history demonstrates that Congress did not contemplate that they would be subjected to judicial scrutiny at a threshold stage.

The review provisions were the product of extensive debate and negotiation in Congress. The reports and discussions on the floor indicate that whereas the proponents of liberal review provisions wished to make every regulation issued by the agency reviewable immediately, the sponsors of the Act were concerned lest a multiplicity of suits frustrate the realization of the legislation's reforms. As a compromise, it was agreed that certain "legislative" regulations could be reviewed in expedited proceedings. Congress must have acted on the premise that such review was generally unavailable under existing law, otherwise the extensive debate over how to limit early access to the courts would have been meaningless.

B. The clause of the judicial review provisions which preserved the "other remedies provided by law" (Section 701(f)(6); p. 72, *infra*) did not make the regulations involved here reviewable prior to their enforcement. The savings clause applied, by its plain terms, to the remedies afforded *in the judicial review section;* no remedies were there afforded with respect to regulations of the kind involved here. We submit that all that Congress intended to preserve in

the savings clause was the right to judicial relief in certain limited extraordinary situations.

C. Subsequent amendments to the Food, Drug and Cosmetic Act demonstrate Congress' continued intention to limit early judicial review to certain major "legislative" regulations. These amendments are particularly significant in light of this Court's earlier conclusion in *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, that review of action by the Food and Drug Administration is to be narrowly confined.

D. Liberal pre-enforcement review would substantially interfere with the administration of the Food, Drug and Cosmetic Act. Many interpretive and procedural regulations have been promulgated and each affects a substantial number of potential plaintiffs. Hence the possibility of a multiplicity of suits is by no means fanciful.

II

The regulations are not, in any event, "ripe" for judicial review. They do not impose a substantial and imminent injury on petitioners, and petitioners have a perfectly adequate remedy if they wait for an enforcement action or seek certification of a new drug. Nor are the regulations "final" in the sense that they reflect the views of the enforcing authority. The Attorney General, and not the Food and Drug Administration, has the power to enforce the Act by seizure or criminal prosecutions. Finally, the factual context of a specific case will assist a reviewing court in determining the proper scope of the statute and its application to the circumstances covered by the regulations.

III

If the Court concludes that the questions presented by petitioners' challenge to the regulations may properly be reviewed at this juncture, we urge that this Court decide the merits so as not unnecessarily to extend this already protracted litigation. On the merits, we believe that the applicable statute (Section 502(e)(1)(B)) was properly construed by the Food and Drug Administration as requiring the established name of a drug to accompany each appearance of the proprietary name on labels or labeling. The legislative history discloses that, after some disagreement between the House and the Senate, a Conference Committee determined that the established name should appear "wherever" the brand name is used. That understanding was confirmed by the remarks on the floor of Congress of Senator Kefauver, a staunch supporter of the legislation.

IV

Venue was improper as to the twenty-six corporate defendants who were not incorporated in Delaware. Section 1391(c) of Title 28 applies, by its terms, only to corporate *defendants*, and no sufficient policy justification has been suggested by petitioners to warrant an expansive reading of that venue provision for purposes of 28 U.S.C. 1391(e).

ARGUMENT

The principal issue in this case is whether the validity of interpretive Food & Drug regulations may be judicially challenged prior to any attempt at en-

forcement in a particular case either through further administrative proceedings or by the institution of civil or criminal actions for non-compliance with their requirements. We concur in the conclusion of the court of appeals—although we reason somewhat differently—that the validity of the "every time" regulations is not subject to review at this pre-enforcement juncture. First, we urge that Congress in the Federal Food, Drug, and Cosmetic Act did not intend that there be judicial review of this kind of regulation ("interpretive" as distinguished from "legislative") prior to its challenge within the framework of a concrete case. As a second independent ground, we argue that, even if the Congressional purpose is not sufficiently plain to draw any dispositive conclusions as to reviewability, review should in any event be deemed presently unavailable since the "every time" regulations are not "ripe" for judicial review.

I

UNDER THE FEDERAL FOOD, DRUG AND COSMETIC ACT CONGRESS DID NOT INTEND TO AUTHORIZE JUDICIAL REVIEW OF THE VALIDITY OF INTERPRETIVE REGULATIONS (SUCH AS THE "EVERY TIME" REGULATIONS INVOLVED HERE) IN ADVANCE OF AN ENFORCEMENT PROCEEDING

There can be no doubt that "[a]ll constitutional questions aside, it is for Congress to determine how the rights which it creates shall be enforced." *Switchmen's Union* v. *National Mediation Board*, 320 U.S. 297, 301. Just as Congress has power to decree that there be no judicial review of administrative action at all (in the absence of a constitutional claim) so

it may determine at what stage of the administrative process judicial review should be available. We submit that the Congressional purpose underlying the judicial review provisions of the Federal Food, Drug and Cosmetic Act—both in its original enactment in 1938 and in later amendments—was to preclude judicial review of the validity of interpretive regulations (such as those involved here) in the abstract, leaving such questions to be determined within the limits of a particular case, sharpened and refined by a particularized factual context.

An analysis of the review provisions of the 1938 Act in light of their substantial legislative history demonstrates, we believe, that Congress was seriously concerned with the possibility that premature judicial intervention might do great harm to the sweeping reforms instituted by the legislation. This history indicates that, after much debate and compromise, Congress determined to confine narrowly the instances in which the Food and Drug Administration's regulations might be reviewed prior to their enforcement. This compromise reflected an awareness of the fact that many provisions of the Act delegated to the agency a quasi-legislative function, and that the persons or corporations subject to such interstitial legislation were entitled to a prompt authoritative determination of the question whether a particular challenged regulation exceeded the power conferred by Congress. The original purpose of the review provisions—to permit judicial supervision of "legislative" regulations—has been carried forward in Congress' later amend-

ments to the Act, which authorize pre-enforcement review only in select cases.

A. THE LEGISLATIVE HISTORY[4] OF SECTION 701(F)(1) AND RELATED PROVISIONS DEMONSTRATES THAT CONGRESS INTENDED SECTION 701(F)(1) TO BE THE EXCLUSIVE AVENUE OF PRE-ENFORCEMENT JUDICIAL REVIEW OF FOOD AND DRUG REGULATIONS IN ALL BUT EXCEPTIONAL CASES.

The only provisions for judicial review of agency regulations in the Federal Food, Drug and Cosmetic Act of 1938 were those appearing in Section 701(f) of the Act, now 21 U.S.C. 371(f) (pp. 71–72, *infra*). Subsection (a) of Section 701 generally authorized the Secretary of Agriculture to promulgate regulations "for the efficient enforcement of this Act" (p. 69, *infra*). Certain kinds of regulations were enumerated in subsection (e) and, with respect to these, the Secretary was directed to convene public hearings in which "any interested person" was entitled to participate. Such regulations were not to be put into effect until ninety days after public issuance of an order based on the hearing. Subsection (f) provided for judicial review, "[i]n a case of actual controversy as to the validity of any order under subsection (e)" if a petition was filed within that 90-day period in a court of appeals. Subsection (f) then concluded with a proviso that "[t]he remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law."

The very specific enumeration in Section 701(e), and Section 701(f)'s limitation of judicial review to

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[4] Dunn, *Federal Food, Drug and Cosmetic Act* (1938) (hereinafter referred to as "*Dunn*") contains the full legislative history of the 1938 Act.

cases "of actual controversy as to the validity of any order under subsection (e)" were not the products of inattentive or hurried draftsmanship; they emerged as a deliberate compromise from the vigorous discussions and disagreements on the floor of Congress and in committee reports over the appropriate nature and extent of pre-enforcement judicial intervention. The view of the strongest proponents of strict regulation was typified by the initial version of the Act, the so-called "Tugwell bill" which was introduced in 1933 at the first session of the Seventy-Third Congress. That bill (S. 1944) contained no provision whatever for judicial review, although it authorized the Secretary of Agriculture to prescribe a wide variety of legislative regulations (*Dunn* 37–50). A successor bill had broad judicial review provisions which empowered district courts "to restrain by injunction * * * the enforcement * * * of any regulation * * * if it is shown that the regulation is unreasonable, arbitrary or capricious, or not in accordance with law * * *." Sec. 23, S. 2000, 73d Cong., 2d Sess. (1934), Dunn 66. See also Sec. 23, S. 2800, 73d Cong., 2d Sess. (1934), *Dunn* 86.[8] Attention was called to this change on the floor of the Senate, and the Senator who had introduced the measure argued that it substantially increased the legislation's fairness and obviated much of the criticisms leveled at the predecessor bill. 78 Cong. Rec. 8958–8959 (1934), *Dunn* 157–159.

[8] These bills also subjected the kinds of regulations now enumerated in Section 701(e) to the approval of a Committee on Public Health and a Committee on Food, which were to be appointed by the President. See *Dunn* 65–66, 69, 85.

Essentially the same broad provision was included in a similar bill introduced in the 74th Congress. Sec. 702, S. 5, 74th Cong., 1st Sess., (1935), *Dunn* 200. The Senate Committee on Commerce then expanded the provision by authorizing district courts not merely to enjoin the enforcement of regulations but also "to grant appropriate injunctive relief from any act or omission of any officer, representative, or employee of the Department in the administration of this Act, if it has been shown that such act or omission is unreasonable, arbitrary, or capricious * * *." *Dunn* 225. The Committee's amendment was approved by the Senate (79 Cong. Rec. 4863 (1935), *Dunn* 330–331) as was the entire bill (79 Cong. Rec. 8356 (1935), *Dunn* 510).

The bill was then sent to the House, where it was thoroughly redrafted by the House Committee on Interstate and Foreign Commerce. The revision eliminated the judicial review provision altogether. H. Rept. No. 2755, 74th Cong., 2d Sess. (1936), pp. 8–9, *Dunn* 542–543. The committee explained that a specific review provision was unnecessary because "[t]here is always an appropriate remedy in equity * * * and furthermore the committee is of the opinion that ample protection is given by the so-called Declaratory Judgments Act * * *." H. Rept. No. 2755, 74th Cong., 2d Sess. (1936), p. 8, *Dunn* 557. After limited discussion, in the course of which the absence of a judicial review provision was attacked (80 Cong. Rec. 10243–10244, *Dunn* 593–594), the House passed its redrafted version (80 Cong. Rec.

10244, *Dunn* 596). In conference, however, the judicial review provision which had passed the Senate was restored. 80 Cong. Rec. 10517, *Dunn* 609. The bill was never enacted, however, because the House and Senate could not agree on whether to assign some duties under the Act to the Federal Trade Commission. 80 Cong. Rec. 10680 (1936), *Dunn* 633.

The bill which was ultimately enacted was introduced in the 75th Congress, 1st Session as S. 5. Subsections (a), (b), (c), and (d) of Section 24 of that bill were substantially identical with the parallel subsections of Section 701 of the Act in its final form (see pp. 69–72, *infra*).* They authorized the Secretary of Agriculture to promulgate regulations "for the efficient enforcement" of the Act. Section 24(c) enumerated certain kinds of regulations—substantially those now listed in Section 701(c)(1) (p. 69, *infra*)—and required public hearings and a 90-day waiting period before such regulations could take effect. *Dunn* 650–651. Section 30 of the bill broadly authorized judicial review, substantially as had been proposed in the legislation which passed the Senate in the prior Congress. District courts were empowered by this bill to enjoin not merely regulations promulgated under Section 24(c), but "any regulation promulgated in accordance with Section 24" (including, in other words, regulations promulgated "for * * * efficient enforcement") and to grant injunctive relief against acts or omissions of officials of the Department of

*In its present form, of course, the Act assigns to the Secretary of Health, Education, and Welfare the duties which had been conferred by the 1938 Act on the Secretary of Agriculture.

Agriculture. *Dunn* 653–654. The bill was amended by the Senate Committee in certain respects which are not relevant here and was passed in the Senate. *Dunn* 746.

The House Committee on Interstate and Foreign Commerce again redrafted the entire bill. This time it did not eliminate the judicial review provision, but substituted an additional subsection in what had been Section 24 in the Senate bill and became Section 701 of the House legislation. That subsection authorized judicial review in a district court "[i]n a case of actual controversy *as to the validity of any order under subsection* (e) * * *." *Dunn* 810–811 (emphasis added).

The accompanying House report (H. Rept. No. 2139, 75th Cong., 3d Sess. (1938), pp. 9–12; *Dunn* 823–824) stated that "Section 701(e), (f), (g) of the committee amendment set forth the procedure governing the formulation and judicial review of certain regulations to be issued by the Secretary" and then significantly pointed out (*Dunn* at 824; emphasis added):

> Such regulations are *not merely interpretive. They have the force and effect of law and must be observed.* Their violation may result in the imposition of criminal penalties, or in the confiscation of the goods involved if shipped in interstate commerce, or in their exclusion from the country if imported.

The report further noted that the special review section would "permit an early determination of the validity of the Secretary's action with respect to any proposal for a regulation, amendment, or repeal, and

make for prompt certainty as to legal rights" (*Dunn* 825). The report noted further, referring to the language which now appears in section 701(f)(6) (p. 72, *infra*), that there "is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding" (*ibid.*). No explanation was offered as to what those rights were and how this procedure fitted into the statutory scheme.

The proposed review provisions met with strong opposition from a minority of the House Committee, the Secretary of Agriculture, the Department of Justice and various consumer organizations. The House minority noted that the review provisions related to regulations the issuance of which went to "the very heart of any worthy food and drug legislation [and that] [i]f the public health and welfare are to be adequately safeguarded, regulations putting these provisions into effect should be promptly and effectively enforceable * * *" (H. Rept. No. 2139, 75th Cong., 3d Sess., Part 2, pp. 1–3, *Dunn* 834). The principal objection of the minority was that district court review could be used as a delaying tactic, seriously impeding the effective enforcement of the Act (*Dunn* 835). It concluded that "the extraordinary provision for court review of regulations in section 701(f), * * * would postpone indefinitely the consumer protection * * *" (*Dunn* 836). In the same vein, the Secretary of Agriculture in a letter to Congressman Mapes, a committee member, pointed out that the regulations covered

by 701(f) review related to the exercise of "quasi-legislative power" to complete and effectuate the congressional will and that if the broad reach of 701(f) providing for district court review were not limited it would so "hamstring" the Act's enforcement "as to amount to a practical nullification of the substantial provisions of the bill" (*Dunn* 836-837). Similar fears were expressed by a wide variety of consumer organizations and members of Congress. See, *e.g.*, 83 Cong. Rec. 7772–7773, 7775–7777, 7779, 7785–7786, 7787–7788, *Dunn* 839–840, 842–845, 858–863, 876–880, 883–884).

On the other hand, the industry pressed for broad pre-enforcement review to forestall any possible usurpation of administrative power by the issuance of regulations having the effect of law without a close judicial check on the exercise of that power. In debating the Committee provision in the House, Congressman Lea (Chairman of the House Committee) stressed that the regulations as to which review was authorized "have the force of law, the same as if enacted by the Congress. In making those regulations the departments act as the agents of Congress," and that "the people deserve protection against arbitrary and capricious government, against inexperience and ignorance by the departments that exercise this semilegislative authority" (83 Cong. Rec. 7775, 7889–7896, *Dunn* 851, 852). Proponents of the broad pre-enforcement review provisions included, for example, fruit and vegetable producers who were concerned lest unreviewable regulations having the force of law limit

the chemical tolerances on sprays which might result in irreparable injury to their businesses (see 83 Cong. Rec. 7781, 7783, 7896–7898, *Dunn* 842–844, 867–868, 871–872, 942, 949–950). During House debate an amendment offered to transfer the review function to the courts of appeals was defeated (83 Cong. Rec. 7892, 7898, *Dunn* 931–932, 950, 962).

The bill then went to a House-Senate Conference Committee which drafted the present Section 701. In pertinent part, the accompanying Conference Report provided (H. Conf. Rept. No. 2716, 75th Cong., 3d Sess. (1938), p. 25; *Dunn* 995–996; emphasis added):

> Judicial review of the Secretary's order putting into effect a regulation under section 701 (e) under the conference agreement is had in the circuit court of appeals * * *
>
> * * * * * * *
>
> The type of judicial review provided in the agreement is as broad as the Constitution permits in the case of review by a constitutional court. *It is to be noted that the function of the Secretary in making regulations and orders to carry them out is legislative in character.* The bill as agreed in conference retains the provisions of the House bill in section 701 (e) which lays down the rules under which the regulations may be formulated and issued. Notice, hearing, and findings are required, and the Secretary must base an order only on substantial evidence of record. Judicial review of the Secretary's action to determine if there has been compliance with such requirements, whether or not there was substantial evidence to support the

findings, and, of course, upon constitutional questions, may be had.

"The provision of the House amendment under which the remedies provided for are in addition to, and not in substitution for, other legal remedies, is retained.

Again there was no elaboration as to the scope and reach of this latter provision, which became section 701(f)(6).

Without debate the compromise was agreed to in the Senate (83 Cong. Rec. 8738, *Dunn* 996). During the House Debate, Congressman Lea—a strong proponent of broad judicial review—noted that the conference was a compromise, and expressed his satisfaction with the judicial review provisions as modified. 83 Cong. Rec. 9096, 9098–9099, *Dunn* 999–1001; see also *Dunn* 1002–1007. At the same time, Congressman Reece noted that the review provisions were "worked out so as to meet with the approval of the Department of Agriculture, which, according to [his] understanding, at no time raised an objection to the bills containing a court-review provision which would enable the orders of the Department to have their validity passed upon before they become effective" (83 Cong. Rec. 9100, *Dunn* 1010). The conference bill was then agreed to (83 Cong. Rec. 9101, 9393, 9502, 9616, *Dunn* 1010, 1014–1015).

Two propositions emerge quite distinctly, we submit, from an examination of the legislative history of this provision of the 1938 Act. *First*, Congress did not believe that judicial review of regulations is

sued by the Food and Drug Administration was generally available at the pre-enforcement stage under existing law, which included the Declaratory Judgments Act, nor did it intend to create any such pre-enforcement rights generally. For had Congress contemplated that regulations such as those involved here and in the *Toilet Goods* cases (Nos. 336 and 438, this Term) could be judicially reviewed at the juncture where review is being sought here, it would hardly have been necessary to spell out, in painstaking detail, the procedure described in subsections (1), (2) and (3) of Section 701(f). Indeed, if Congress contemplated judicial review in the circumstances of this case and of *Toilet Goods*, and if it intended to preserve that remedy in subsection (f)(6)—the view of the court of appeals in the *Toilet Goods* decision, 360 F. 2d 677, 683–684, which petitioners adopt here (Pet. Br. 31–36)—it was engaging in a meaningless exercise when it provided so precisely in subsections (1), (2) and (3) for judicial review of certain kinds of regulations enumerated in subsection (e).

The enumerated regulations have an immediate and direct impact on the persons subject to them and since they are promulgated only after a full public hearing they reflect, at least as fully as do the regulations here, the considered judgment of the Food and Drug Administration. A decision adopting the standards urged by petitioners (Pet. Br. 27–30) and holding that the "every time" regulations involved here were intended to be judicially reviewable prior to enforcement would necessarily mean that the regulations enumerated in subsection (e) are similarly judicially

reviewable, even without the special authorizing provisions of subsections (f)(1)–(f)(3). But this would render meaningless the 90-day limitation of subsection (f)(1) and the thrust of the legislative debate culminating in the adoption of the rule requiring review in the court of appeals. Both of these requirements were plainly designed to insure that the legality of any challenged regulation would be expeditiously determined. See H. Rept. No. 2139, 75th Cong., 3d Sess. (1938), pp. 10–12; *Dunn* 824–826. Any person interested in delaying a judicial test of this kind of regulation could, however, under petitioners' view, wait until long after the 90-day period, and then institute a declaratory judgment suit in a district court.

Moreover, had Congress believed that a declaratory-judgment remedy was available under existing law to a person challenging any of the regulations enumerated in subsection (e), it would have been accomplishing no more by enacting sections (f)(1)–(f)(3) than providing a choice of forum to the plaintiff in such a suit. The legislative history of the review provisions indicate that Congress' purpose in vesting jurisdiction in the court of appeals was not only to expedite the review proceeding but also to meet the objections of the minority members of the House Committee who were concerned that "a single district judge could be found who would issue an injunction" against the enforcement of a regulation and who therefore opposed any provision which would "clothe each and every district judge with authority to block the enforcement of a regulation throughout the United States." H. Rept. No. 2139, Part 2, 75th

Cong., 3d Sess. (1938), p. 2; *Dunn* 835. Obviously Congress would not have been foreclosing that possibility, which concerned representatives of the Executive branch as well as legislators,[7] by merely providing an alternative remedy which a plaintiff could pursue if he chose. Congress must have assumed, we submit, that the review procedure outlined in sections 701(f)(1)–(f)(3) would be the exclusive remedy in the great majority of instances where promulgated regulations were challenged prior to enforcement.

Second, the salient legislative material shows that dispute in Congress over the review provisions was keyed to those regulations which were "legislative in character" and had "the force and effect of law." H. Rept. No. 2716, 75th Cong., 3d Sess. (1938), p. 25, *Dunn* 995. On the one hand, the Secretary of Agriculture and consumer organizations were seriously concerned that broad pre-enforcement district court review of this type of regulation would hobble the effective administration of the Act. On the other hand, it was precisely as to this type of administrative action that the industry representatives were most desirous of obtaining pre-enforcement review and thereby eliminating what they deemed to be a real threat of unbridled administrative power. In section 710(f), Congress struck a balance between the conflicting interests. Pre-enforcement review of the most significant "legislative" regulations—those which were

[7] See letter from the Secretary of Agriculture, H. Rept. No. 2139, Part 2, 75th Cong., 3d Sess. (1938), pp. 3–4; *Dunn* 838–839, and memorandum from the Department of Justice, 83 Cong. Rec. 7892–7893; *Dunn* 933–934; see also 83 Cong. Rec. 7785, *Dunn* 875–876.

promulgated under a specific Congressional grant of authority to the Secretary to set standards having the force and effect of a statute[8] was allowed, but only in the courts of appeals and only within 90 days after their issuance.[9]

The legislative history we have summarized above establishes, we believe, that this is a case of what Professor Jaffe has characterized as "implied statutory exclusion" of judicial review; it illustrates his proposition that a "statute may provide for review of an 'order' upon a record made at a hearing, from which it may be inferred that an order not based on a hearing is nonreviewable." Jaffe, *Judicial Control of*

[8] For a discussion of the difference between "legislative" and "interpretive" regulations see *Gibson Wine Co.* v. *Snyder*, 194 F. 2d 329, 331–332 (C.A.D.C.); see also, Davis, *Administrative Rules—Interpretative, Legislative, and Retroactive*, 57 Yale L. J. 919, 928–929 (1948), particularly at 932 noting with regard to the Federal Food, Drug and Cosmetic Act that the distinctions between the two types "are very real, not merely theoretical;" 1 Davis, *Administrative Law* (1958) §§ 5.03–5.04.

See also the Report of the Attorney General's Committee on Administrative Procedure (1941) pp. 99–100 (as quoted in *American President Lines, Ltd.* v. *Federal Maritime Commission*, 316 F. 2d 419, 422, n. 5 (C.A.D.C.)): "Administrative rule making, * * * includes the formulation of *both legally binding regulations* and *interpretative regulations*. The former receive statutory force upon going into effect. The latter do not receive statutory force and their validity is subject to challenge in any court proceeding in which their application may be in question" (emphasis added).

[9] Not all legislative regulations were made judicially reviewable in this fashion. The Secretary's power to promulgate regulations providing exemptions from labeling requirements where it was impracticable to comply was not made subject to the hearing procedures prescribed by subsection (a) or to the review procedures of subsection (f).

Administrative Action (1965), pp. 357–358. We emphasize that Congress did not thereby foreclose all review of regulations or orders not specifically covered by subsection (f)(1); it merely deferred such judicial scrutiny until after the agency had undertaken to enforce its announced policy. Hence this is not a case, as was *Leedom* v. *Kyne*, 358 U.S. 184, where the refusal to permit judicial review at this juncture "would mean 'a sacrifice or obliteration of a right which Congress' has given * * *." 358 U.S. at 190. At most, it means that the right, if it exists, is vindicated later, rather than now.

What we urge here with respect to the judicial review provisions of the Food, Drug and Cosmetic Act of 1938 is what this Court held those provisions to mean in *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594. In that case this Court held that a finding by the Food and Drug Administration of probable cause to seize articles as misbranded was not reviewable prior to the libel action which followed the administrative seizures. Although the Court recognized that the seizures might themselves "cause irreparable damage to a business" (339 U.S. at 599), it found that judicial review was unavailable to prevent the seizures because (339 U.S. at 600–601, emphasis added):

> Judicial review of this preliminary phase of the administrative procedure does not fit the statutory scheme nor serve the policy of the Act. Congress made numerous administrative determinations under the Act reviewable by the courts. But it did not place the finding of probable cause under § 304(a) in that category. *This highly selective manner in which Congress has provided for judicial review reinforces the*

inference that the only review of the issue of probable cause which Congress granted was the one provided in the libel suit. Cf. *Switchmen's Union* v. *Board*, 320 U.S. 297, 305–306.[10]

The *Switchmen's Union* case, on which the Court relied in *Mytinger*, stands for the same proposition—that Congress' specific enumeration of judicial remedies in a statute may be construed, where the legislative history permits, as an implied denial of any other review.

This case is governed by the same principles as were applied in *Mytinger*. Here, as in that case, the regulation represents only the view of the administrative agency; actual enforcement is in the hands of the Attorney General. 339 U.S. at 598–599. The regulations at issue here are as much a "preliminary step" (339 U.S. at 600) as the finding of probable cause in *Mytinger*. In both cases, that step may have a direct and meaningful impact on those subject to it; in *Mytinger* eleven administrative seizures of the plaintiff's product had been made within a matter of months (339 U.S. at 596). Despite this immediate effect the Court held that the plaintiff in *Mytinger* was obliged by the statutory review scheme to wait until the libel proceeding was conducted and to interpose his legal claim at that time.

Indeed, the present case involves administrative action which is even more "preliminary" than that in *Mytinger*, for the regulations here are merely the foundation for potential findings of probable cause on which future seizures may be made. Quite plainly,

[10] In a footnote, the Court noted that an order refusing a new drug application is reviewable, and that other orders relating to the regulations enumerated in Section 701(e) are also made reviewable 339 U.S. at 600–601, n. 6.

if the Food and Drug Administration had reached the conclusions stated in these regulations as an internal policy decision and not by the issuance of interpretive rules, findings of probable cause based on those conclusions would be squarely controlled, insofar as judicial review is concerned, by the *Mytinger* decision. We submit that the Food and Drug Administration's decision to publicize its interpretation of the statute after giving interested partes an opportunty to participate in their promulgation should not make reviewable the kind of threshhold decision which Congress intended to shield against the delays of immediate litigation.

B. NO DIFFERENT LEGISLATIVE INTENTION CAN BE INFERRED FROM THE ENACTMENT OF SECTION 701(f)(6)

Petitioners contend that by enacting the savings clause which appears as subsection (f)(6), Congress manifested its intention not to make the procedure outlined in subsections (f)(1)–(f)(3) the exclusive route by which pre-enforcement review could be obtained (Pet. Br. 31–36). The same view was expressed by the court of appeals in the *Toilet Goods* case (360 F. 2d at 683–684). But this argument overlooks the fact that subsection (f)(6), by its plain terms, saves only alternative remedies to those "provided for in *this* subsection"—*i.e.*, it preserves the pre-existing rights of plaintiffs challenging the regulations enumerated in subsection (e). Only those plaintiffs are accorded remedies in "*this* subsection." Subsection (f)(6) neither expressly nor impliedly deals with review of interpretive regulations such as those involved here. Nor does it even affect legisla-

tive regulations other than those specifically enumerated in subsection (e). And, as we have shown, the disagreement in Congress over the scope of subsection (f)(1) makes sense only if Congress assumed that without express legislation very few regulations would be judicially reviewable prior to enforcement.

This limited construction of subsection (f)(6) is consistent with its particular development in the legislative history of the statute. In the earlier versions of the Food, Drug and Cosmetic Act, the only remedy explicitly preserved was the "right of any person against whom a criminal prosecution or suit for injunction shall have been brought under this act or who shall intervene as claimant in any proceeding of libel for condemnation to plead that the regulation whose violation is alleged as the ground for such prosecution, suit, or libel, is invalid * * *" (*Dunn* 184, 225, 609–610). To this purely defensive remedy Congress also added, in the final versions of the bill, "whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding." H. Rept. No. 2139, 75th Cong., 3d Sess. (1938), p. 11, *Dunn* 825. We believe that the failure to refer to these rights explicitly in earlier drafts indicates that Congress viewed these rights narrowly and did not contemplate that either a "historical proceeding in equity" or "a declaratory judgment proceeding" could be brought simply because the agency had, on due deliberation, promulgated a regulation which was likely to affect the plaintiff's method of doing business. It must be recalled,

in this regard, that the Act was passed at a time when this Court was firmly establishing the doctrine that federal courts should not interfere prematurely in administrative proceedings. See *e.g., Myers* v. *Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50–51, decided just six months before the passage of the Food, Drug and Cosmetic Act.

What Congress had in mind in enacting subsection (f)(6) was to preserve the right to bring suit to challenge regulations promulgated under subsection (e) in exceptional instances where review under subsection (f)(1) might be unavailable. If, for example, the Food and Drug Administration undertook to promulgate legislative regulations without affording an opportunity for public participation (which would include general notice of the proposal and an opportunity to file objections and request a public hearing) an equity proceeding or a declaratory judgment action brought after the 90-day period might be entertained on the ground that the statutory procedures had not been followed. Cf. *United States* v. *3-7/12 Dozen Packages*, 59 F. Supp. 284, 289 (W.D. La), affirmed *sub nom. Byrd* v. *United States*, 154 F. 2d 62, 64 (C.A. 5); *United States* v. *Bodine Produce Co.*, 206 F. Supp. 201, 204 (D. Ariz.). But see *United States* v. *Lord-Mott Co.*, 57 F. Supp. 128 (D. Md.).

C. IN AMENDING THE ACT, SUBSEQUENT CONGRESSES HAVE MANIFESTED A SIMILAR INTENTION TO LIMIT PRE-ENFORCEMENT JUDICIAL REVIEW

Additional compelling evidence that the 1938 Act should be read as denying pre-enforcement review for

the interpretive regulations involved here emerges from an examination of the pattern by which subsequent Congresses have amended the original statute. The amendments have consistently specified the regulations which are subject to judicial review either under Section 701(f) or under specific provisions in the amendments and have been silent as to all others. The Insulin Amendments of 1941, for example (55 Stat. 851, 21 U.S.C. 356), authorized the promulgation of regulations "necessary to carry out the purposes of this section," but specified that Section 701(e) and (f) was to apply to such regulations only "insofar as they prescribe tests or methods of assay to determine strength, quality, or purity of any drug, different from the tests or methods of assay set forth for such drug in an official compendium, * * *."

In the Pesticide Chemicals Amendments of 1954 (68 Stat. 511, 21 U.S.C. 346a), Congress also provided a detailed pre-enforcement judicial review procedure for specifically enumerated kinds of orders. The review provisions, which contemplate a 60-day limitation period and expedite ultimate determination of the claim by conferring jurisdiction on the court of appeals, cannot be squared with the proposition that Congress was saving to all parties affected by a regulation the right to sue in the district court at any time before enforcement under the Declaratory Judgment Act.

The Color Additive Amendments of 1960 (74 Stat. 397, 21 U.S.C. 376) also provided that Sections 701(e) and (f) were to apply to certain of the regulations authorized by that statute but excluded from the specific enumeration the regulations applicable to exemptions

and to fees. Here again, the fair inference is that Congress was intending to make only the former subject to pre-enforcement judicial review.

Finally, the highly selective approach was followed in the Drug Amendments of 1962, which include the provision giving rise to the present dispute. Under the 1962 statute, the Secretary is authorized to adopt varied regulations, but only some are explicitly subject to formal rule-making procedures and to pre-enforcement judicial review.[11]

The 1954, 1960 and 1962 amendments are particularly significant in this regard because they followed this Court's decision in *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594. In the *Mytinger* decision this Court narrowly construed the review provisions of the 1938 Act and held, in effect, that where review was not specifically provided, it was barred. See pp. 24–26, *supra*. By following the same pattern in amendments to the Act, and specifically in the provisions relevant here, Congress was, we submit, ratifying this Court's understanding of the statute. This reference is buttressed by Congress' repeated refusal, through the years, to accede to industry requests for specific statutory provisions giving district courts the authority to hear pre-enforcement review action brought by affected parties.[12]

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[11] See, for example, Sections 505, 508(a); 76 Stat. 784, 789. Neither Section 502(e)(1)(B) nor 502(n)(1)—the "established name" provisions under which the "every time" regulations were promulgated—refer in the portions pertinent here, to regulations, the order of their adoption, or to judicial review.

[12] See, *e.g.*, Hearings Before a Subcommittee of the House Committee on Interstate and Foreign Commerce on H.R. 4277

D. LIBERAL PRE-ENFORCEMENT REVIEW OF INTERPRETIVE AND MINOR LEGISLATIVE REGULATIONS WOULD INTERFERE WITH THE EFFICIENT ENFORCEMENT OF THE FOOD, DRUG AND COSMETIC ACT.

The limiting construction of the review provisions which we are urging here is consistent with Congress' obvious desire to establish a regulatory system which would permit as little delay as possible in the execution of the legislative objectives. Congress fixed extremely brief limitation periods for the review of those regulations which were explicitly made reviewable by Section 701(e) and (f), and in the debates over the breadth of the judicial review clause all legislators seemed to be agreed that it was desiable not to permit "the machinery [to be] hung up over long periods of time" (83 Cong. Rec. 7894, *Dunn* 939; see also 83 Cong. Rec. 7894–7895, *Dunn* 940–941).[12]

(an early draft of the "Pesticide Chemical Amendments of 1954," 68 Stat. 511), 83d Cong., 1st Sess. (1953), p. 28, *et seq.*; see also H. Rept. No. 1385, 83d Cong., 2d Sess., pp. 10–11.

[12] It is true, as petitioners argue (Pet. Br. 35), that Congressman Mapes asserted during the House debates that "existing law" permitted any individual to sue the Food and Drug Administration in his home district on the ground that an order applicable to him was "arbitrary, capricious, unreasonable, or contrary to law." 83 Cong. Rec. 7893, *Dunn* 936. But his views were almost immediately challenged. Congressman Leavy specifically responded, "I take issue with the gentlemen who say you can go into any Federal court and there get an injunction against an agent of the United States Government, for official actions." 83 Cong. Rec. 7895, *Dunn* 941. Citing the doctrine of sovereign immunity, Representative Leavy "challenged" Representative Mapes "to cite authority authorizing such general actions, as he refers to in his remarks, where the citizen can institute suit against the United States." *Ibid.* And it is not entirely irrelevant, in this regard, that the amendment in support of which Representative Mapes made the quoted assertion was defeated at the conclusion of the debate by a substantial margin. (See p. 18, *supra*).

It requires little elaboration to demonstrate that a rule of review such as petitioners are urging in this case would substantially affect the administration of the Food and Drug Act. In administering the provisions of the statute, the agency is called upon to make many interpretive rulings and to issue various regulations under Section 701(a) for the "efficient enforcement" of the Act. Part 3 of title 21 of the Code of Federal Regulations, for example, contained, as of January 1966, seventy different "Statements of General Policy or Interpretation" (21 C.F.R. 3.1–3.700), relating to widely varying subjects—*e.g.*, the use in drug manufacture of ox bile from condemned livers of slaughtered animals (21 C.F.R. 3.16) and the quantity of egg which must be present in a shampoo preparation for it to qualify as "egg shampoo" (21 C.F.R. 3.651). These regulations were issued voluntarily as guides to industry; the Food and Drug Administration was under no legal obligation to promulgate them as it did. Their publication is, however, obviously beneficial. It gives the industry an opportunity voluntarily to conform its practices to the views of the agency or to point out informally how and why the agency's position is unsound or imposes an excessive practical burden.

Many other regulations promulgated under Section 701(a) are scattered throughout title 21 of the Code of Federal Regulations, and it would cast a very heavy burden on the agency if it were obliged to litigate the validity of every clause of every regulation immediately upon publication. The burden would, of course, fall with equal weight on the courts which

would have the responsibility of adjudicating all these disputes.

Multiplicity of suits is not a remote possibility. In the present case, as in the *Toilet Goods* cases, suit was brought by a industry-wide association on behalf of all its members. But nothing in the Declaratory Judgments Act or in the rule proposed by petitioners limits this remedy to an industry-wide suit. If pre-enforcement review were held to be available for the reasons urged by petitioners, each of the plaintiffs in this action and in *Toilet Goods* would be able to sue separately in the district where that plaintiff resided. (see 28 U.S.C. 1391(e), pp. 72–73, *infra*). A judgment in favor of the Food and Drug Administration in any one of such actions would not, of course, be binding in a suit brought by another plaintiff in a different district. The debates in both legislative chambers before the passage of the 1938 Act demonstrate, we believe, a consensus within Congress that such multiplicity of suits and the resulting uncertainty would seriously impair the effectiveness of the statute. It is for this reason that, even with respect to important legislative regulations, Congress provided a 90-day limitations period for review and conferred jurisdiction on the courts of appeals.

To be sure, pre-enforcement review of legislative regulations has a disruptive effect on the administration of the Act and imposes a heavy burden on the agency and the courts. There is, however, a stronger justification for pre-enforcement review of legislative regulations. When Congress has delegated to an agency the power to promulgate specific rules to ex-

ecute a general legislative policy, the very issuance of the rules imposes legal duties on the individuals or corporations who produce or market the product which is affected. So long as the rules are fairly within the limits of the power which Congress has conferred, they will be sustained and they must, therefore, be obeyed. See, *e.g.*, *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218. But interpretive regulations merely announce the agency's understanding of a statutory obligation; the duty is imposed by the statute itself, and the agency's construction adds to it only such weight as a reasoned and presumably expert opinion may carry.

The legislative history shows, we believe, that Congress weighed the disruptive effect which pre-enforcement review would have on the administration of the Act against the interests of the industry's members in obtaining a judicial determination of the agency's power before having to comply at their peril. Where it had broadly delegated power to the agency, Congress decided that it was best, notwithstanding the delay that might be caused, to allow pre-enforcement review of regulations which were "legislative in character." H. Rept. No. 2716, 75th Cong., 3d Sess. (1938), p. 25, *Dunn* 995. This was a safeguard against abuse of the sweeping power given to the Food and Drug Administration, but it carried with it an implied rejection of the right collaterally to attack such regulations after the time to review them had expired. *United States* v. *8-7/12 Dozen Packages*, 59 F. Supp. 284 (W.D. La.), affirmed *sub nom. Byrd* v. *United States*, 154 F. 2d 62 (C.A. 5); *United*

States v. *Bodine Produce Co.*, 206 F. Supp. 201 (D. Ariz.). But see *United States* v. *Lord-Mott Co.*, 57 F. Supp. 128 (D. Md.).

As for interpretive or minor legislative regulations, neither Congress nor industry was concerned over the possibilities of abuse. Obviously the agency could not, by an interpretive regulation, convert a lawful product into an unlawful one. Nor could it, by exercising most of the limited quasi-legislative power delegated to it to issue regulations governing exceptions, substantially affect production or marketing within any of the regulated industries. With respect to such regulations it was Congress' intent, we submit, to deny all relief prior to enforcement. To construe the Act otherwise is to confer a broader power of early review, with more serious disruptive effects, when the consequence of the agency action is slight than when its pronouncement has the force of a statute.

II

THE REGULATIONS AT ISSUE HERE ARE NOT RIPE FOR JUDICIAL REVIEW

We argue alternatively that, irrespective of the precise terms or legislative history of the Federal Food, Drug and Cosmetic Act's judicial review provisions, the juncture at which review of the regulations is being sought here is an inappropriate one under the principles governing "ripeness" which have been judicially developed in decisions of this Court. By "ripeness" we mean the doctrine by which courts determine whether review of administrative action is

justified *"now* rather than *later."* Jaffe, *Judicial Control of Administrative Action* (1965) (hereinafter *"Jaffe"*), pp. 411–412, n. 63 (emphasis in the original). We believe that an evaluation of the cluster of judicially recognized considerations which enter into a determination of whether a controversy is "ripe" for judicial decision warrants the conclusion that the present dispute is premature so long as it is divorced from the specific factual context that could be presented in an enforcement proceeding.[14]

We begin with the proposition that it is ordinarily desirable to limit judicial review of administrative rule-making to factually sharpened instances where legal rights are directly at issue. Administrative agencies have been created by Congress to deal, in a specialized way, with a broad complex of subjects ranging, for example, from security regulation to patrolling labor-management disputes. Their major tool is an expertise refined by a continuing dialogue with a particular segment of the economy. Courts should not prematurely intrude on this dialogue, but should limit their intervention to the instances in which negotiation has failed.[15]

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[14] An enforcement case would arise if the penalty provisions of the Act were invoked (*i.e.*, injunction, condemnation or criminal prosecution, Sections 301–307, 21 U.S.C. 331–337). Alternatively, judicial review of the regulation would follow administrative procedures relating to new drug clearance (Section 505, 21 U.S.C. 355) or antibiotic certification (Section 507, 21 U.S.C. 357).

[15] "Negotiation is *the* major mode of administration, of resolving the continuous uncertainties of fact and law. If it is made too easy to bring every administrative expression, how-

The doctrine of "ripeness" enables the judiciary to stay its hand until the time for its entry is appropriate. In determining whether a plaintiff's challenge to an agency's action is "ripe" or "premature," emphasis has usually been placed on the three considerations we discuss below. No precise formula for determining whether a particular controversy is ripe is available, of course. As Professor Jaffe has observed, "[R]ipeness should not be determined by formula but by a reasoned balancing of certain typical and relevant factors for and against the assumption of jurisdiction." *Jaffe*, 396.

Before turning to a discussion of these elements, we emphasize that our compartmentalization is employed solely for the sake of clarity. The elements overlap and complement each other; it is in their varied combinations and permutations—not by any formalized listing—that one finds answers to questions of early reviewability. As Mr. Justice Frankfurter put the matter in *Poe* v. *Ullman*, 367 U.S. 497, 508–509:

> Justiciability is of course not a legal concept with a fixed content or susceptible of scientific verification. Its utilization is the resultant of many subtle pressures, including the appropriateness of the issues for discussion by this Court and the actual hardship to the litigants of denying them the relief sought.

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ever informal, into court, negotiations may be hampered." *Jaffe*, 410–411 (emphasis in the original); see also *Helco Products Co.* v. *McNutt*, 137 F. 2d 681 (C.A.D.C.).

See similarly his concurring opinion in *Joint Anti-Fascist Refugee Committee* v. *McGrath*, 341 U.S. 123, 149, 155–157."

A. THE REGULATIONS DO NOT PRESENT AN IMMINENT AND SUBSTANTIAL DANGER TO ANY LEGALLY COGNIZABLE INTEREST OF PETITIONERS

1. The nature and extent of the impact which challenged regulations have on those subject to the contested administrative action is plainly an essential consideration in determining ripeness. Particularly when, as here, there is ample opportunity to challenge the regulation at a later point in time, *i.e.*, after a more individualized determination by the agency, at-large regulations should not be reviewable unless they "disrupt * * * and seriously disorganize * * * business," *Columbia Broadcasting System, Inc.* v. *United States*, 316 U.S. 407, 414, or constitute an attempt to "control the business affairs" of the party seeking relief to the

[16] We also observe, at the outset, that the Declaratory Judgments Act does not compel a court to assume jurisdiction where a case is not otherwise ripe for review. It is settled that the Act "is not an independent source of federal jurisdiction." *Schilling* v. *Rogers*, 363 U.S. 666, 677; *Great Lakes Co.* v. *Huffman*, 319 U.S. 293, 300; *Alabama State Federation of Labor* v. *McAdory*, 325 U.S. 450, 461. By the same token, Section 10 of the Administrative Procedure Act, recodified as 5 U.S.C. 704, authorizing review of "final agency action," does not of itself compel review if the agency action is not "ripe." Compare the decisions so holding in "standing" cases. *Kansas City Power & Light Company* v. *McKay*, 225 F. 2d 924 (C.A.D.C.), certiorari denied, 373 U.S. 914; *Ove Gustavsson Contracting Company* v. *Floete*, 278 F. 2d 912, 914 (C.A. 2), certiorari denied, 364 U.S. 894. We do not read *Cappadora* v. *Celebrezze*, 356 F. 2d 1 (C.A. 2), as embracing contrary principles. In that case, although the Social Security Act did not provide for review on a decision not to reopen, the decision had become a "final and binding" determination so that it was reviewable under the Administrative Procedure Act.

extent that it "cannot cogently plan its present or future operations," *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192, 199–200. See *Frozen Food Express* v. *United States*, 351 U.S. 40, 44. Highly illuminating in this regard is the decision in *Shields* v. *Utah Idaho Central R. Co.*, 305 U.S. 177, which concerned administrative action affecting the complainant railroad's status under many other regulatory statutes. The Court held that the plaintiff was entitled to relief because the interconnected provisions of the various federal statutes made the administrative determination a very significant one to the railroad. 305 U.S. at 182–184. See also *A.F. of L.* v. *Watson*, 327 U.S. 582, 593–596; cf. *Frozen Food Express* v. *United States*, 351 U.S. 40; *McCulloch* v. *Sociedad Nacional*, 372 U.S. 10, 16–17.

A corollary to this proposition is that judicial intervention is not warranted where the injury to the challenging party is not significant. Courts should be hesitant to step in at an early stage where the challenged regulation affects an enterprise only in a peripheral or indirect way, reaches only a narrow phase of a party's business, creates only a minor inconvenience, or requires an adjustment which does not have an impact on the fundamental structure of a business operation.[17]

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[17] Broad-reaching administrative action may be deemed ripe for immediate review where it is patently invalid on its face. See, *e.g.*, *Public Utilities Commission* v. *United Fuel Gas Co.*, 317 U.S. [illegible], 469; *Leedom* v. *Kyne*, 358 U.S. 184; *Farmer* v. *United Electrical Radio & Machine Workers*, 211 F. 2d 36, 39 (C.A.D.C.), certiorari denied, 347 U.S. 943. Review in such circumstances would be justified on principles analogous to those

Another factor which may properly be considered is the availability and efficacy of other remedies. There may be instances in which the consequences of failure to comply with the administrative directive are so severe and immediate that no realistic remedy can be said to exist at the termination of the administrative process. Thus, no test of validity may ever arise in a specific case because the party affected by the administrative action may deem compliance the only way "to avoid the unpleasant legal consequences which failure to conform entails." *Columbia Broadcasting System, Inc.* v. *United States, supra,* 316 U.S. at 417; *Bantam Books, Inc.* v. *Sullivan, supra,* 372 U.S. at 64–65, n. 6.

2. Under these standards, petitioners have not shown any compelling need for immediate review. They allege that the regulation would require them to discard their present promotional materials and to change existing labels (R. 14–16; Pet. Br. 13).[18] But mere financial expense has generally not been held a justification for early judicial intervention. *Perkins* v. *Lukens Steel Co.,* 310 U.S. 113, 125; *Allen* v. *Grand Central Aircraft Co.,* 347 U.S. 535, 539–540, and cases

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which authorize judicial intervention to strike down patently unconstitutional statutes where the very imminence of enforcement stifles the exercise of basic rights. *E.g., Dombrowski* v. *Pfister,* 380 U.S. 479; *Truax* v. *Raich,* 239 U.S. 33, 38–39; *Pierce* v. *Society of Sisters,* 268 U.S. 510, 534–536; cf. *Bantam Books, Inc.* v. *Sullivan,* 372 U.S. 58.

[18] The additional allegation that the regulations would render labels "confusing and repetitious" or misleading (R. 15) does not, of course, bear on whether review should be had now or later. If confusion is caused by the regulations, it is the public, not petitioners, who suffer the irreparable injury.

there cited. And it seems quite plain that petitioners have an adequate remedy if they continue to use their present promotional material—in accordance with their understanding of the statute—and await enforcement actions. Indeed, since the drug-clearance provisions of Section 505 (21 U.S.C. 355) and the antibiotic certification procedures of Section 507 (21 U.S.C. 357) permit pre-marketing determinations, petitioners appear to have a satisfactory remedy which would not require them to wait for an administrative seizure.

The suggestion that the drug industry may be deterred by the risk of criminal prosecution from ever testing the validity of these regulations if review is denied at this juncture is totally unreal. It is not the policy of the Food and Drug Administration to proceed in the first instance by way of criminal sanctions when, as the district court's decision discloses to be true here, its reading of the statute is subject to differences of opinion. Indeed, if this Court sustains our position on the procedural issue, it is the intention of the Food and Drug Administrator to test the validity of the regulations under the new drug-clearance provisions of Section 505 of the Act, 21 U.S.C. 355 (which provides for direct appeal to the court of appeals (Section 505(h)) or under the antibiotic certification provision of Section 507, 21 U.S.C. 357 (which also provides for direct review in the court of appeals after the administrative process has concluded and before the administrator's orders have become effective (Section 507(f)).[19]

[19] If, for unanticipated reasons, court enforcement becomes necessary, the Department of Justice will proceed only civilly.

We note further in this connection that the regulations are not, on their face, blatantly improper. See note 17, *supra*. Indeed, as we argue below (pp. 55–62, *infra*), they reflect a proper understanding of the legislative purpose and are supported by the legislative history of the Drug Amendments.

B. THE REGULATIONS DO NOT REFLECT THE FINAL JUDGMENT OF THE ENFORCING AUTHORITY

1. Only "final" agency action, as contrasted with preliminary or tentative expression of agency views, is entitled to judicial review. By "final" we mean that kind of action which justifies the conclusion that at no future time will the plaintiff suffer an impact "more conclusive, definite or substantial." *Joint Anti-Fascist Refugee Committee* v. *McGrath*, 341 U.S. 123, 149, 154, n. 4 (concurring opinion). The reason for this limitation is that the agency charged with administration of a regulatory statute must be accorded the opportunity to adjust its tentative views in light of the broad challenges which are asserted. Essentially, the same rationale underlies the "exhaustion of administrative remedies" doctrine (*e.g.*, *Myers* v. *Bethlehem Shipbuilding Corp.*, 303 U.S. 41, 50–52) which requires a party contesting an administrative decision to pursue existing administrative remedies to determine whether he will ever feel the "pinch of

for an injunction (Section 302, 21 U.S.C. 332) or by condemnation (Section 304, 21 U.S.C. 334). Multiple administrative seizures would ordinarily be unavailable since it is doubtful that there is probable cause to believe that the misbranded article is dangerous to health or that the labeling is fraudulent, misleading or injurious. See Section 304(a).

administrative action." *Federal Power Commission* v. *Hope Gas Co.*, 320 U.S. 591, 619; *Whitehouse* v. *Illinois Central R.R. Co.*, 349 U.S. 366, 373. See also *Rabinowitz* v. *Kennedy*, 376 U.S. 605, 610–611, where this Court held unripe one aspect of a declaratory judgment action challenging the administrative interpretation of the Foreign Agents Registration Act of 1938 because the claimants had failed to make any effort to determine how much information they would be required to disclose.[20]

The requirement of "finality" likewise affords the agency the freedom to develop a solution to public problems without fear that its every action will be subject to minute judicial scrutiny. Uniform, forceful and creative administration would be frustrated by easy access to the courts every time a person is affected by half-formed administrative action. For example, in *Eccles* v. *Peoples Bank*, 333 U.S. 426, the plaintiff's membership as a bank in the Federal Reserve System was conditioned by the Board of Governors on its independence from the control of holding companies. When a holding company obtained an interest in violation of this condition, the Board refused to relieve the bank of the condition but disavowed any intent to invoke it unless the public interest required such action. On that record this Court denied petitioner's request that it declare the condi-

[20] See also, *Danville Tobacco Association* v. *Freeman*, 351 F. 2d 832, 833 (C.A.D.C.), where, among the court's reasons for finding lack of ripeness as to certain appellants, was their failure to make application to see if they met the requirements of certain tobacco regulations which they were challenging judicially.

tion invalid. In reaching this conclusion, the Court pointed out that no administrative action had come to "fruition" and that "when a body such as the Federal Reserve Board has not only not asserted a challenged power but has expressly disclaimed its intention to go beyond the legitimate 'public interest' confided to it, a court should stay its hand," 333 U.S. at 434–435. See also *Continental Bank & Trust Company* v. *Martin*, 303 F. 2d 214, 218 (C.A.D.C.).

In short, the more tentative and preliminary the agency action, the less reason there is for judicial interference. In *United States* v. *Los Angeles R.R. Co.*, 273 U.S. 299, the "final valuation" sought to be reviewed was "only a preliminary, interim step toward possible future action." *Federal Power Commission* v. *Hope Gas Co.*, 320 U.S. 591, 619. Similarly, this Court's *per curiam* decision in *Public Utilities Commission* v. *United Air Lines*, 346 U.S. 402, appears to have rested on the ground that the administrative order being challenged—which directed the airline to file tariffs with the State commission—may not have reflected the final and considered views of the agency regarding its jurisdiction. This is also the essence of the much-cited case of *Helco Products Co.* v. *McNutt*, 137 F. 2d 681 (C.A. D.C.), where declaratory relief was sought challenging (1) a "letter" of the legal staff of the Food and Drug Administration concerning the statutory validity of a certain proposed shipment in interstate commerce, (2) a follow-up letter from the Food and Drug Administrator agreeing that the shipment would violate the Act, and (3) the refusal of the Attorney

General to advise petitioner if prosecution or other sanction would follow if such shipment was made. In refusing judicial review in such circumstances, the court pointed out (137 F. 2d at 684):

> To permit suits for declaratory judgments upon mere informal, advisory, administrative opinions might well discourage the practice of giving such opinions, with a net loss of far greater proportions to the average citizen than any possible gain which could accrue.[21]

Compare *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, 599–600.[22]

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[21] Similar holdings of non-finality were made in *Richfield Oil Corp.* v. *United States*, 207 F. 2d 864, 870 (C.A. 9); *American President Lines, Ltd.* v. *Federal Maritime Commission*, 316 F. 2d 419 (C.A.D.C.); *First Savings and Loan Association of the Bahamas, Ltd.* v. *Securities and Exchange Commission*, 358 F. 2d 358 (C.A. 5).

[22] There are, it is true, instances in which non-final agency action might be deemed "ripe" simply because the question is of great importance beyond the dispute of the parties before the court. Where an agency proposes far-reaching implementation of a statute through the adoption of regulations, public as well as private interests may best be served by having disputed issues as to the validity of the agency's actions settled at the threshold. Early legitimization of far-reaching agency action may avoid time-delaying multiplicity of litigation and give the agency an authoritative basis for proceeding in a manner that will best serve a significant public interest. Thus, in *McCulloch* v. *Sociedad Nacional*, 372 U.S. 10, the courts intervened in the early stages of National Labor Relations Board proceedings to hold that the Board had misinterpreted the National Labor Relations Act to cover maritime operations of foreign flag ships employing alien seamen. This Court recognized that the usual rule has been to avoid premature review in the labor-management field, but held that that case warranted a different approach because of the "overriding consideration * * * that the Board's assertion of power to determine the representation of foreign seamen aboard vessels under

2. We agree, of course, that the regulations involved in the present case are the product of mature administrative judgment, and are not merely preliminary or tentative agency conclusions. This does not, however, *ipso facto* render them "final" within the meaning of the criteria we have outlined above. An important element in the finality of such a regulation is the question whether the agency whose voice is heard in the regulation is the same agency to whose hands the enforcement of the statute has been entrusted. In *Frozen Food Express* v. *United States*, 351 U.S. 40, this Court held reviewable an interpretive regulation of the Interstate Commerce Commission construing the "agricultural exemption" of the Motor Carrier Act of 1935. In discussing wherein the regulation was appropriate for judicial review the Court said (351 U.S. at 44):

> Where unauthorized operations occur, the Commission may proceed administratively and issue

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foreign flags has aroused vigorous protests from foreign governments and created international problems for our Government" (372 U.S. at 16–17). The Court further said (372 U.S. at 17):

> Important interests of the immediate parties are of course at stake. But the presence of public questions particularly high in the scale of our national interest because of their international complexion is a uniquely compelling justification for prompt judicial resolution of the controversy over the Board's power.

See also *Trans World Airlines, Inc.* v. *C.A.B.*, 339 F. 2d 56, 63 (C.A. 2), certiorari denied, 382 U.S. 842; *Northeast Airlines, Inc.* v. *C.A.B.*, 345 F. 2d 662, 664–665 (C.A. 1); cf. *Brigham* v. *F.C.C.*, 276 F. 2d 628 (C.A. 5).

a cease and desist order. § 204(c). Such orders of the Commission are enforceable by the courts. § 222(b). And wilful violation of a cease and desist order is ground for revocation of a certificate or permit. § 212. The determination made by the Commission is not therefore abstract, theoretical, or academic.

Under the Federal Food, Drug & Cosmetic Act, however, the enforcement authority is lodged with the Attorney General and not with the Food and Drug Administration. And this particular separation of interpretation and enforcement powers has been deemed by this Court an indication that a challenge to administrative action alone might be premature: "Whether a suit will be instituted depends on the Attorney General, not on the administrative agency. He may or may not accept the agency's recommendation. If he does, seizures are made and libels are instituted. But the seizures and suits are dependent on the discretion of the Attorney General." *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, 599; see also *Helco Products Co.* v. *McNutt*, 137 F. 2d 681, 683 (C.A.D.C.).[22]

We also note that petitioners have never requested the Secretary of Health, Education and Welfare to establish "exemptions" from the "every time" reg-

[22] We do not in any way mean to suggest that the Attorney General does not act on the recommendations of the Food and Drug Commissioner or that there is any difference in view on how to proceed in this case. We mean only to note that even in its most final aspect—when it is fully matured agency action—there is still a preliminary cast to the instant regulations which differentiates them from the regulation in *Frozen Food*.

ulations on grounds of impracticability, as he is authorized to do under Section 502(e)(1)(B) of the Act. See *Rabinowitz* v. *Kennedy*, 376 U.S. 605, 610–611.[24]

C. THE FACTUAL CONTEXT OF A SPECIFIC CASE CAN CONTRIBUTE TO AN UNDERSTANDING OF THE ISSUES PRESENTED BY A CHALLENGE TO THE VALIDITY OF THE REGULATIONS

1. A significant "ripeness" factor in the field of public law is that the issue put to the court for decision should be definite and clear-cut. It is not the business of courts to decide unreal or cloudy controversies. See, *e.g.*, *United Public Workers* v. *Mitchell*, 330 U.S. 75; *Rescue Army* v. *Municipal Court*, 331 U.S. 549; *Public Service Commission* v. *Wycoff*, 344 U.S. 237; *Alabama State Federation of Labor* v. *McAdory*, 325 U.S. 450; *International Longshoremen's Union* v. *Boyd*, 347 U.S. 222; *Poe* v. *Ullman*, 367 U.S. 497; *Rabinowitz* v. *Kennedy*, 376 U.S. 605. While this doctrine has had its primary application in constitutional adjudication, it has also been recognized that "[c]ourts should avoid passing on questions of public law even short of constitutionality that are not immediately pressing." *Eccles* v. *Peoples Bank*, 333 U.S. 426, 432. Adjudication, in short, must rest on "an adequate and full-bodied record" particularly in the resolution of "delicate problems" which are "bound to have far-reaching import." *Public Affairs Press* v. *Rickover*, 369 U.S. 111, 113.

[24] This is relevant only with respect to the regulation (21 C.F.R. 1.04(g)(1)) relating to the labeling requirements of Section 502(e)(1). Section 502(n) has no exemption provision with respect to advertising material, probably because impracticability was not anticipated as a basis for noncompliance with that provision.

Factual considerations are important in another sense. Interpretive regulations, before their enforcement in a particular case, are general in their application. They cut across a wide range of varied factual situations. The question of their validity cannot, therefore, usually be determined independently of factual variables. A court must "see what legal issues it is deciding, what effect its decision will have on the adversaries, and some useful purpose to be achieved in deciding them." *Public Service Commission* v. *Wycoff*, 344 U.S. 237, 244; *United Public Workers* v. *Mitchell*, 330 U.S. 75, 90. Just as an agency could not go into court to obtain the court's seal of approval on its at-large interpretation of a statute, so is it usually impossible to determine in advance, at the behest of a private party, whether the agency's interpretation is wrong. Only if all conceivable facts to which a regulation might apply are known can a court decide with certainty whether the regulation properly interprets the statute. See, *e.g.*, *Aetna Life Insurance Co.* v. *Haworth*, 300 U.S. 227, 242, where the Court granted declaratory relief in "an adjudication of present right upon *established* facts" (emphasis added); *Pierce* v. *Society of Sisters*, 268 U.S. 510, 530, where the Court took the unusual course of striking down a statute before its enforcement where there were no "controverted questions of fact." A court may otherwise be confident of a regulation's application to most foreseeable cases, but it cannot predict with certainty whether the regulation can properly govern *all* conceivable possibilities which come within its terms.

Asking a court to make such a determination is, in effect, requesting an advisory opinion.

2. The present case illustrates, quite graphically, the inappropriateness of permitting an abstract determination of the kind sought here. The applicable statute declares drugs misbranded if their labeling does not comply with the statute. Under ordinary circumstances, the statute would be construed by a court, with the assistance of the interpretation provided by the Food and Drug Administration, in a proceeding involving the particular label or promotional labeling of a drug manufacturer or marketer. The question would then be whether the labeling meets the standards of the statute.

In the present proceeding, however, the roles of the parties have been reversed. The question is whether the governmental agency's "every time" regulation is a proper construction of the statute. In arguing that it is not, petitioners have taken three different positions: In the district court they contended that the Food and Drug Administration had the authority to regulate on the question of how prominently the generic name must appear, but that the "every time" regulation went too far (R. 30-31). In the court of appeals, petitioners argued that the statute was satisfied if the established or generic name appeared *once*, in a prominent location, on the labelling and promotional material (Ct. of App. Br. 33, 40, 42). And in the petition for a writ of certiorari it was urged that the statute would be satisfied if the established name appeared prominently "on every page in the required type size" (Pet. 11).

By resolving the issue as it did, the district court adopted none of these three positions. Consequently, petitioners, even if they prevail, are given no guidance as to the standard which the statute establishes. If the agency then issues another interpretive regulation, that too might be successfully challenged without resulting in any standard for the industry to follow.

Indeed, a more serious problem would be presented if a district court were to determine that an agency's interpretation of a statute might be warranted under some circumstances but not under others. Should it then grant relief of the kind sought here by petitioners on the ground that the regulation is not universally applicable or should it deny relief because the regulation is valid as applied to many of the foreseeable situations to which it might relate? We submit that the course chosen by this Court in *Zemel* v. *Rusk*, 381 U.S. 1, 19–20, is the appropriate one—to leave to "a concrete fact situation" the adjudication of the meaning of a statute which might conceivably be applied differently to varying circumstances.

D. PRIOR DECISIONS OF THIS COURT DO NOT CONTROL THE RIPENESS ISSUE IN THIS CASE

Petitioners contend that the "ripeness" or "justiciability" issue in this case is controlled by *Columbia Broadcasting System, Inc.* v. *United States*, 316 U.S. 407; *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192; and *Frozen Food Express* v. *United States*, 351 U.S. 40 (Pet. Br. 17–20). We believe that the three cited decisions are all distinguishable from the present case.

1. In *Columbia Broadcasting System Inc.* v. *United States*, 316 U.S. 407, the Federal Communications Commission, in an attempt to curtail the monopolistic power of networks, issued the "Chain-Broadcasting" regulations controlling contracts between licensees and the networks. Despite the fact that the Commission termed the regulations an expression of "general policy" to be followed in "exercising our licensing power" (316 U.S. at 411, 422), and had issued a "supplementary minute" providing administrative and judicial proceedings whereby individual licensees could challenge the validity of the regulations (316 U.S. at 413–414), this Court permitted early review. It found that, in fact, the regulations were final administrative action (316 U.S. at 422); that if implemented "in accordance with their terms [they] would disrupt appellant's broadcasting system and seriously disorganize its business" (316 U.S. at 414); and that their validity could be fairly assessed only in a direct proceeding in which the network was the true party in interest and was not merely intervening in a licensing proceeding in which the issue might never arise (316 U.S. at 422–423). It was, in short, in very special circumstances where questions of "standing" merged with those of "ripeness"[25] and sweeping agency action was at issue, that the Court permitted judicial intervention.

[25] Professor Jaffe has noted that the question of standing *vel non* was "more acute" than that of ripeness since "[t]o deny relief here may be equivalent to a denial of all relief, in sum to a decision that the network has no 'legally protected interest.'" *Jaffe*, 402.

2. The decision in *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192, was an application of the *Columbia Broadcasting System* rationale. In *Storer*, after extensive hearings, the Federal Communications Commission adopted regulations limiting the number of television stations individuals could own and providing that certain stock interests would amount to ownership. Again rejecting the argument that reviewability was unavailable to a claimant (who, if the regulations were enforced, would lose his license) because the regulations themselves did not, in a formal sense, carry a sanction for non-compliance, the Court pointed out that "final agency action was involved" (351 U.S. at 198) and that unless the licensee had an opportunity to review the validity of the agency action it "cannot cogently plan its present or future operations" (351 U.S. at 200). In *Storer*, as in *Columbia Broadcasting System*, the plaintiff was put to Hobson's choice: it could refuse to comply with the agency's regulation and thereby disqualify itself, if the regulation were sustained, from future benefits, or it might comply and thereby forfeit all opportunity ever to attack the regulation. Petitioners in the present case, as we have shown (pp. 40–42, *supra*), are put to no such difficult dilemma.

3. *Frozen Food Express* v. *United States*, 351 U.S. 40, involved an interpretive regulation concerning the scope of the "agricultural commodities" exemption in the Motor Carrier Act (351 U.S. at 41–42). The Interstate Commerce Commission itself urged early review of its regulation, pointing out that "[t]he interpretation of this agricultural commodity exemption is

of daily importance in the administration of the Act—both to the Commission and to the transportation industry." The Commission asserted that it was "high time, 20 years after enactment of the Motor Carrier Act of 1935, that the scope of the agricultural commodity exemption was settled," so as to avoid "a considerable number of court proceedings as to the status of individual commodities" (Brief for the Interstate Commerce Commission, Nos. 158–164, O.T. 1955, pp. 18, 34). Confronted with this unusual invitation from the agency charged with the enforcement of the Act requesting the resolution of a perplexing controversy, the Court found the administrative action reviewable because it went to the "basis for carriers in ordering and arranging their affairs" and because it "touches vital interests of carriers and shippers alike and sets the standard for shaping the manner in which an important segment of the trucking business will be done," 351 U.S. at 44. *Frozen Food* did involve "interpretive" rather than "legislative" regulations, and thus may properly be said to stand for the proposition that the interpretive nature of regulations is not an absolute bar to review. We do not believe, however, that the decision can properly be read (as Professor Jaffe warned that it might) as holding "that *a regulation of any agency is as such reviewable* as against a claim that it is not ripe." *Jaffe*, 407 [emphasis in original]. The fact that *Frozen Food* was not intended to throw open the courts to premature challenges to administrative action is shown by the Court's careful distinction of *United States* v. *Los Angeles & Salt Lake R. Co.*, 273 U.S. 299 (see 351

U.S. at 43–44). *Frozen Food* holds only that where all other elements of "ripeness" are present, the fact that regulations are interpretive will not necessarily preclude early review."

III

THE REGULATIONS CORRECTLY INTERPRET THE STATUTE AND SHOULD BE SUSTAINED IN THE EVENT THAT THIS COURT REACHES THAT ISSUE

If the Court rejects the arguments we have presented above and holds that review of the validity of these regulations at the present juncture is permitted by the Food, Drug and Cosmetic Act and that the issue is presently ripe for judicial consideration, we believe it would be appropriate for the Court to reach the merits and pass on the validity of the regulations. Our reasons for suggesting this course are the following: The record is complete if no factual development is required; the issue is purely legal and requires no weighing of testimony or other evidence; the district court reached and decided the question; and the action

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[20] The courts of appeals which have had occasion to apply and construe *Frozen Food* in a variety of factual circumstances have not given it an open-ended effect. See, *e.g.*, *Continental Bank and Trust Company* v. *Martin*, 303 F. 2d 214, 217 (C.A.D.C.); (holding an order of the Federal Reserve Board not subject to early review); *National Van Lines, Inc.* v. *United States*, 326 F. 2d 362, 367 (C.A. 7) (holding tariff orders of the Interstate Commerce Commission reviewable where the orders were issued because of the "admittedly inadvertent omission of a footnote to a tariff"); *Trans World Airlines, Inc.* v. *C.A.B.*, 339 F. 2d 56, 63 (C.A. 2), certiorari denied, *sub nom. Hughes Tool Co.* v. *Trans World Airlines, Inc.*, 382 U.S. 842 (holding a C.A.B. order subject to review where it "made an authoritative pronouncement on which important transactions are likely to depend.")

is already three years old and is likely to be much older before it is finally resolved if this Court were to remand the case to the court of appeals. Since the question would be purely one of statutory construction and it concerns nearly all of the drug industry, it is not unlikely that however the court of appeals resolves the underlying issue the case will once again appear in this Court. There is a public interest in enforcing the regulations if they be valid, and we therefore urge the Court not to defer resolution of that question.

On the merits, we believe that the regulations correctly implement the legislative purpose expressed in Sections 502(e)(1)(B) and 502(n)(1) of the Drug Amendments of 1962, 21 U.S.C. 352(e)(1)(B) and 352(n)(1) (pp. 68–69, *infra*).

1. The text of the statute supports the administrative interpretation embodied in the challenged regulations. Section 502(e)(1)(B) [27] of the Act provides that a drug is to be deemed misbranded unless

> (B) for *any* prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on *any* labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for *any* proprietary name or designation for such drug or ingredient:
>
> * * * * *
>
> and *Provided*, That to the extent that compliance with * * * clause (B) of this subpara-

[27] Section 502(n)(1) relating to drug advertising—the other statutory provision involved here—uses the same pattern of language and our argument of Congressional intent applies equally to it. We focus on 502(e)(1)(B) simply because it is that section upon which the legislative history centered.

graph is impracticable, exemptions shall be established by regulations promulgated by the Secretary [emphasis added].

By requiring that the type be at least half as large as that used for "any" proprietary name Congress was necessarily directing that the established name appear every time that the proprietary name appears. For if the statute were satisfied by one or two appearances of the established name on every label or promotional piece, the word "any" would be totally confusing. Would it mean that the established name was to appear in type half the size of the *largest* proprietary name or half the size of the *smallest*? Or would it mean what Congress could plainly not have intended—*i.e.*, that the drug manufacturer could select *any* proprietary name on the label, including the very smallest one, and print the established name in type half that size?

We submit that Congress intended that the word "any" carry the same meaning throughout the statutory provision. Section 502(e)(1)(B) applies to "any" prescription drug—plainly meaning "all" prescription drugs. It covers "any" labeling—again obviously directed to "all" labeling. And it commands that the established name appear in at least half the size of "any" proprietary name—that is a reference, we submit, to "all" proprietary names appearing on the labeling. Cf. *United States* v. *Gertz*, 249 F. 2d 662, 665 (C.A. 9).

There is no substance to the district court's suggestion that the statutory requirement that the established name appear "prominently" would be super-

fluous if the statute itself contemplated an "every time" obligation (R. 54). For even if the "every time" requirement is met, it is still possible for the established name to be printed in such a fashion as to be illegible or unnoticeable. It could, for example, appear in light ink, or a label might be designed which would obscure it by superimposing portions of a design, drawing or photograph over every appearance of the established name. Or, indeed, the type on the label, including the proprietary name, might be so small that type half the size would be almost illegible. It was to insure against the ingenuity of advertising and layout designers that Congress also required that the established name be "prominent."

2. The legislative history plainly supports the Food and Drug Administration's interpretation. As originally approved by the Senate Judiciary Committee, the provisions here involved were not a part of the bill. Instead, the proposed draft contained only the requirement that the established name of any drug appear on the label under the standard of Section 502(c), 21 U.S.C. 352(c), as enacted in 1938—*i.e.*, "prominently." Upon reconsideration, the committee reported a bill which contained the language here involved. This report stated (S. Rept. No. 1744, Part 2, 87th Cong., 2d Sess., p. 8; emphasis added):

> The substitute committee amendment * * * would require that the label bear the "established" name of the drug and the established name of each active ingredient * * *. It would also require that on labels and on any labeling, *wherever* a trade or brand name is used, the established name, as defined in this section,

must be shown in type at least one-half as large as that used for the trade or brand name.

The bill reported by the House Committee on Interstate and Foreign Commerce (H.R. 11581) was similar to the Senate recommendation insofar as it required that the established name be printed on the label "in type at least half as large as that used thereon for any proprietary name * * *." It differed from the Senate version, however, in that it contained no similar requirement as to "labeling."[28] 108 Cong. Rec. 21076. Thereafter, Congressman O'Brien offered an amendment on the House floor which brought labeling within the scope of the Act. It was weaker than the Senate draft, however, in that it required the appearance of the established name on labeling only once or twice—"at the first place, and at the most conspicuous place if other than the first place" where the trade name was used. The House approved the amendment in this form. 108 Cong. Rec. 21081.

This difference between the House and Senate bills was thereafter resolved in favor of the Senate version. See H. Rep. No. 2526, 87th Cong., 2d Sess., Statement of the Managers on the Part of the House, pp. 23–24. The significance of this Conference Report was explained in the Senate by Senator Kefauver—the leading sponsor of the legislation—as follows (108 Cong. Rec. 22039; emphasis added):

[28] "Labeling" is defined in Section 201(m), 21 U.S.C. 321(m), to include all "other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

> In this section both the Senate and House versions were identical with one exception. This was a limitation upon the frequency with which the established name should appear in labeling, which among other things includes direct mail advertisements, brochures, pamphlets, and so forth; under the limitation the established name would have had to be printed only "at the first place, and at the most conspicuous place if other than the first place, at which such proprietary name for such drug or ingredient, as the case may be, is used." This limitation was not accepted by the conferees. *Thus the established name of a prescription drug must appear in type at least half as large as the trade name wherever the latter is used in drug promotional matter, including package inserts, and so forth.*

The word "wherever" in both the Senate report and in Senator Kefauver's remarks demonstrates conclusively, we submit, that the sponsors of the legislation contemplated that every appearance of the proprietary name on labels or labeling would have to be accompanied, in type at least half the size, by the established name of the drug. That this was the intention of those who were interested in the legislation was reaffirmed by Congressman O'Brien who, during hearings before a recent House committee, observed that the "every time" regulations properly reflected the results of the Conference Committee's deliberations. See Hearings Before a Subcommittee of the House Committee on Interstate and Foreign Commerce on H.R. 2410, 89th Cong., 1st Sess. (1963), pp. 297–298.

Petitioners' assertion that the regulation imposes an unreasonable hardship is patently unsound. It was Congress' intention to encourage physicians to think of prescription drugs in terms of their established names, not by the brand names which the drug companies attached to their products. As Senator Hart, one of the legislation's sponsors, put it (108 Cong. Rec. 17383):

> This bill recognizes the transcendent importance of generic names if the American people are to have good drugs at reasonable prices, and it seeks to end the failure to disclose generic names, whether that failure is intentional or unintentional.

This course was deemed necessary by Congress to achieve the result which it felt the nation's consumers were entitled to—realistic prices for drugs.[29] To achieve this end Congress could, for example, have prohibited the use of brand names (as distinguished from manufacturers' names) altogether on labels or labeling; instead it chose to associate the generic name with the brand name selected by the manufacturers. We submit that a most reasonable way to foster the mental association which Congress wished to promote is by the "every time" requirement of these regulations.

Moreover, this case involves a "contemporaneous construction of the Act by the agency entrusted with

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[29] It was brought out in the congressional debates that drugs could be purchased under their generic names at one-third or one-half the price of the same drug sold under a trade name. See 108 Cong. Rec. 17367–17368, 17381–17383. See also the views of Senators Kefauver, Dodd, Carroll, Hart, and Long, pp. 33–36, 38–39, 46–51, S. Rept. 1744, Part I, 87th Cong., 2d Sess. (1962).

its administration." *Federal Housing Administration* v. *The Darlington, Inc.*, 358 U.S. 84, 90. Cf. *Consolo* v. *Federal Maritime Commission*, 383 U.S. 607, 621. Whatever weight that construction might be given in the abstract is underscored when, as here, a basis for the challenge is that it imposes a severe burden on the industry and renders its labels illegible. The Food and Drug Administration is in constant touch with the drug industry and it is better able to judge than the courts whether there is substance to such claims. In the present case it promulgated these regulations after public proceedings, and they are substantially supported by the legislative history and purpose of the statute.

IV

VENUE WAS IMPROPER AS TO TWENTY-SIX CORPORATE PLAINTIFFS NOT INCORPORATED IN DELAWARE

The remaining issue in this case concerns the scope of the venue provisions of 28 U.S.C. 1391(e)(4) (pp. 72–73, *infra*). The finding of both courts below that venue was improper as to certain plaintiffs was, we submit, entirely correct. It accorded with the settled rule that unless Congress manifests a clear intent to the contrary, the "residence" of a corporation for venue purposes is the place of its incorporation. *Federal Power Commission* v. *Texaco, Inc.*, 377 U.S. 33, 37–39; cf. *Suttle* v. *Reich Brothers Construction Co.*, 333 U.S. 163, 166. There is no persuasive evidence, we submit, that a contrary intent has ever been manifested by Congress for purposes of Section 1391(e)(4)—*i.e.*, when the corporation is a plaintiff.

The core of petitioner's argument (Pet. Br. 40–46)—and that of the authorities which they cite—is that when Congress in 1948 revised the venue provisions of 28 U.S.C. 1391(c) as to corporate defendants, it also intended the same result as to corporate plaintiffs. Section 1391(c) provides that a corporate defendant is suable not only in the judicial district where it is incorporated but also where it is "licensed to do business or is doing business." It then concludes "and such judicial district shall be regarded as the residence of such corporation for venue purposes." Some courts have said that this latter clause would be meaningless if it were not construed as changing the venue rules as to corporate plaintiffs. See, *e.g.*, *Freiday* v. *Cowden*, 83 F. Supp. 516, 517–518 (S.D.N.Y.); *Southern Paperboard Corporation* v. *United States*, 127 F. Supp. 649, 650 (S.D.N.Y.).

The more authoritative [30] and, we believe, the better reasoned authority is that no such broad reading of Section 1391(c) is justified. The words used in the second clause are restrictive; they refer to "such" corporations not to "all" or "any" corporations, and they appear to relate back to the first clause, which plainly covers only corporate defendants. Nor, given the historical framework, does our reading render the second clause meaningless. In 1939, this Court amelio-

[30] The only courts of appeals which considered the scope of 1391(c) have agreed with the courts below and held that it refers only to the venue of corporate defendants. *Robert E. Lee & Co.* v. *Veatch*, 301 F. 2d 434 (C.A. 4), certiorari denied, 371 U.S. 813; *Carter-Beveridge Drilling Co.* v. *Hughes*, 323 F. 2d 417 (C.A. 5); cf. *Lumbermens Mut. Cas. Co.* v. *South Portland Engineering Co.*, 252 F. Supp 149 (S.D.N.Y.).

rated the rigors of the rule that corporations could be sued only in the State and judicial district in which they were chartered by holding that this requirement was waived when a corporation appointed an agent to receive service of process in the State and district in which it was doing business. *Neirbo Co.* v. *Bethlehem Shipbuilding Corp.*, 308 U.S. 165. However, on the eve of the 1948 revision of Title 28, this Court limited the waiver doctrine by holding that it did not apply in a suit against multiple defendants (one of which was a corporation) where venue as to non-resident defendants rested on the corporation's "residence" in that district. *Suttle* v. *Reich Brothers Construction Co.*, 333 U.S. 163. The second clause of Section 1391(c) was clearly intended to change the result in *Suttle*. See *Robert E. Lee & Co.* v. *Veatch*, 301 F. 2d 434 (C.A. 4), certiorari denied, 371 U.S. 813. As an authoritative commentator put it, the second "clause serves a purpose in laying venue, in a transitory action, in defendant's [corporation's] district where there are multiple defendants residing in different districts of the same state; and also in the case where defendants reside in different divisions of the same district or different districts in the same state." 1 *Moore's Federal Practice* (2d ed. 1964) 1503.

Moreover there is no indication in the history of 28 U.S.C. 1391(e) that Congress would have wanted to change the residence limitations as to plaintiff corporations[21] for purposes of the suits covered by this pro-

[21] "The principal demand for this proposed legislation comes from those who wish to seek review of decisions relating to public lands, such as the awarding of oil and gas leases, consideration

vision, as it had previously done under 1391(e) with respect to corporate defendants. The necessary consequence of petitioners' position is to authorize "forum-shopping" for no legitimate purpose. Congress never intended to permit that result.

CONCLUSION

For the foregoing reasons it is respectfully submitted that the judgment of the court of appeals should be affirmed.

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of land patent applications and the granting of grazing rights or other interests in the public domain." S. Rep. No. 1992, to accompany H.R. 1960, 87th Cong., 2d Sess., p. 6; H. Rep. No. 536, to accompany H.R. 1960, 87th Cong, 1st Sess., p. 3. Both reports also refer to congestion in the District of Columbia which, prior to the amendment, was the only district where a case such as this could have been brought.